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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/985,699	11/05/2001	Mark Pepys	P 0284057 206002/JND	4029
909	7590	02/18/2005	EXAMINER	
PILLSBURY WINTHROP, LLP			MELLER, MICHAEL V	
P.O. BOX 10500			ART UNIT	
MCLEAN, VA 22102			PAPER NUMBER	
			1654	
DATE MAILED: 02/18/2005				

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/985,699

Applicant(s)

PEPYS, MARK

Examiner

Michael V. Meller

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 11/29/2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 18-47 is/are pending in the application.
- 4a) Of the above claim(s) 21-23, 25, 27, 29-39, 41, 43, 45 and 47 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 18-20, 24, 26, 28, 40, 42, 44, 46 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|-----------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u> </u> | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION***Election/Restrictions***

The invention is drawn to many different compounds (disease associated proteins and non-proteinaceous agents) which are contained in many different compositions used to treat a patient in the instant claims. The compounds vary distinctly in their structures and functions. Thus, an individual search is required of each individual compound. Therefore, as part of electing one of the groups as the elected invention (applicant elected Group II, claims 18-35 in a previous response), Applicant is also required to elect two specific compounds as noted above, to which the elected invention will only be examined on the merits as drawn to; as well as identifying those claims to which the elected compound is drawn. Other compounds will not be examined are considered. This requirement is not to be taken as an election of species, but rather as an election of a single invention, since each compound is assumed to be a patentably distinct invention, in the absence of evidence to the contrary.

On 2/16/2005, Charles Rories elected the non-proteinaceous agent as the agent in claim 20 and the disease associated protein as SAP (serum amyloid P component) by telephone.

Applicant's election of Group II, claims 18-35 on the record is acknowledged.

Claims 21-23, 25, 27, 29-39, 41, 43, 45, 47 are withdrawn from further consideration as being drawn to non-elected subject matter. The other compounds

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encompassed by the other claims 18-20, 24, 26, 28, 44, 46 which are not the agent of claim 20 or SAP will not be examined or considered. Applicant is reminded that this is a restriction and not an election of species and thus the other compounds and non-elected claims will not be considered or examined in this application.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 18-20, 24, 26, 28, 40, 42, 44, 46 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hertel et al. (see abstract, col. 4, bottom of columns 39-40 and top of column 41) taken with Van Kessel et al. (see abstract, col. 1, col. 3, top of col. 5).

Hertel teaches to administer the claimed compound of claim 20 (the elected agent) to a patient for treating diseases associated with amyloidosis such as Alzheimer's disease. Hertel teaches to administer the claimed agent of claim 20 to treat such a condition. Hertel even states that the compounds administered are used to prevent the interaction of SAP with amyloid fibrils. The reference does not teach to monitor the clearance of the SAP (the elected disease associated protein) from the patient's plasma.

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Van Kessel teaches to quantify the concentration of SAP as noted on col. 5, lines 1-20. Van Kessel also notes that deposits of amyloid beta-protein is the primary event causing Alzheimer's disease. Thus, since SAP when it binds to amyloid fibrils is not wanted since this leads to Alzheimer's as noted by Hertel then it would have been obvious to monitor the clearance of Sap from the plasma of the patient since Van Kessel teaches that SAP is quantified and thus it would have been obvious to monitor it since it is unwanted otherwise Alzheimer's will occur.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael V. Meller whose telephone number is 571-272-0967. The examiner can normally be reached on Monday thru Thursday: 9:30am-6:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Bruce Campell can be reached on 571-272-0974. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

A handwritten signature in black ink, appearing to read 'M. Meller', with a long horizontal flourish extending to the right.

Michael V. Meller
Primary Examiner
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MVM